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L9: Entry 23 of 107 File: PGPB Dec 26, 2002

DOCUMENT-IDENTIFIER: US 20020198486 A1
TITLE: Method of drug delivery to interstitial regions of the myocardium

Summary of Invention Paragraph:
[0004] Local drug delivery to the heart is known. In U.S. Pat. No. 5,551,427, issued to Altman, implantable substrates for local drug delivery at a depth within the heart are described. The patent shows an implantable helically coiled injection needle which can be screwed into the heart wall and connected to an implanted drug reservoir outside the heart. This system allows injection of drugs directly into the wall of the heart acutely by injection from the proximal end, or on an ongoing basis by a proximally located implantable subcutaneous port reservoir, or pumping mechanism. The patent also describes implantable structures coated with coating which releases bioactive agents into the myocardium. This drug delivery may be performed by a number of techniques, among them infusion through a fluid pathway, and delivery from controlled release matrices at a depth within the heart. Controlled release matrices are drug polymer composites in which a pharmacological agent is dispersed throughout a pharmacologically inert polymer substrate. Sustained drug release takes place via particle dissolution and slowed diffusion through the pores of the base polymer. Pending application Ser. Nos. 08/8816850 by Altman and Altman, and 09/057,060 by Altman describes some additional techniques for delivering pharmacological agents locally to the heart. Implantable drug delivery systems, such as controlled release matrices, have been well described in the literature, as has the use of delivering particulate delivery systems or particulate drug carriers such as microcapsules, lipid emulsions, microspheres, nanocapsules, liposomes, and lipoproteins into the circulating blood. However, local delivery of such micro drug delivery systems to a depth within the myocardium using endocardial catheter delivery and epicardial injection systems have not been described, and have many advantages that have not been foreseen.

Detail Description Paragraph:
[0019] The microspheres to be used in this treatment are manufactured to be large enough to prevent migration within the myocardial interstitium, but also small enough to be deliverable by a catheter fluid pathway to a depth with the myocardium. Microspheres such as Alkerme's (Cambridge, Mass.) Prolease system enables freeze dried protein powder to be homogenized in organic solvent and sprayed to manufacture microspheres in the range of 20 to 90 um (microns). Development of such microsphere depots for sustained release of proteins with unaltered integrity requires methods to maintain stability during purification, storage, during encapsulation, and after administration. Many of these techniques have been recently summarized in the literature. See, e.g., Scott D. Putney, and Paul A. Burke: Improving protein therapeutics with sustained release formulations, Nature Biotechnology, Volume 16, February 1998, 153-157. Issues associated with degradation for biodegradable polymers used in such microspheres are also well known [Robert Miller, John Brady, and Duane E. Cutright: Degradation Rates of Oral Resorbabale Implants {Polylactates and Polyglycolates}: Rate Modification and Changes in PLA/PGA Copolymer Ratios, J. Biomed. Mater. Res., Vol. II, PP. 711-719 (1977). The value of delivering microsphere encapsulated macromolecular agents such as proteins bFGF and VEGF to a depth within the heart muscle for controlled release have not been described, and have substantial unrecognized benefits over other delivery approaches.

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L9: Entry 36 of 107 File: PGPB May 9, 2002

DOCUMENT-IDENTIFIER: US 20020055721 A1
TITLE: Biocompatible pharmaceutical articles

Detail Description Paragraph:
[0048] Specific pharmaceutical articles that are appropriate for the practice of the present invention include the following: (1) manufacturing articles, including fermentors, glassware, plasticware, probes and tubing; (2) storage and transport articles, including storage vessels, transport vessels, stoppers, lids and septums; (3) analytical articles including needles, pipette tips, cell culture apparatus and analytical equipment; (4) medical devices, including conventional needle syringes, hypodermic needles, intravenous injection devices, biopsy needles and devices, tissue ablation devices, aspirating needles, catheters, including endoluminal catheters such as needle injection catheters (for endocardial, epicardial, and pericardial agent administration), balloon catheters and diagnostic catheters and perfusion catheters, filters, grafts, metallic and polymeric stents, including those having a polymer coated thereon for delivery of pharmaceutically active materials, aneurysm filling coils, transmyocardial revascularization devices, percutaneous myocardial revascularization devices, soft tissue clips, sutures, blood clot filters, implants or spikes (polymeric or metallic); and (5) medical device accessories, including adhesives, coatings, balloons, membranes, manifolds, hubs, fittings, stopcocks, valves, tubing kits, manifolds, wires, syringes, microspheres or nanoparticles, and so forth.

Detail Description Paragraph:
[0122] Viral and non-viral gene vector solutions were incubated (a) in a polypropylene control vial, (b) in an untreated needle injection catheter like that of Example 1, and (c) in a needle injection catheter like that of Example 1, which has been lined with Pebax.RTM. 5533, a polyether block amide. Pebax.RTM. polymers are available from Elf-Atochem.

Detail Description Paragraph:
[0138] In this Example, an adenoviral solution with an initial titer of 1.0.times.10.sup.9 IU/ml, was incubated for 30 minutes at 37.degree. C. in association with the following: (1) needle injection catheter, like that of Example 1, (2) a PTFE plug (3/8 inch diameter.times.1 inch long cylinder), (3) an FEP plug (3/8 inch diameter.times.1 inch long cylinder) (4) a 0.013 inch ID.times.0.025 inch OD.times.30 cm length tube coated with Xylan-8110, a PTFE polymer available from Whitford Co in a coating formulation available from Thermech, (5) a 0.013 inch ID.times.0.025 inch OD.times.30 cm length tube coated with Xylan-1220, a FEP polymer available from Whitford Co., which is formulated in a coating available from Thermech, (6) a 0.013 inch ID.times.0.025 inch OD.times.30 cm length tube constructed from FEP available from Endura, (7) a stainless steel tube lined with PTFE liner (ca 0.01" ID), (8) a lumen of PTFE having an internal diameter of 0.012 inch, (9) a lumen of PTFE having an internal diameter of 0.015 inch. The control is a polypropylene tube. After incubation, vector activity was assessed using the techniques of Example 1.

Detail Description Paragraph:
[0140] The virus compatibility experiments revealed no significant difference between these teflon-coated surfaces and the bare needle injection catheter.

Elemental analysis (ICP and X-ray diffraction) of the lumens detected a spectrum of metal species (Cr, Fe, Mn, Ni, and Ti) on all coated surfaces. Although the ICP results varied within a treatment group (also observed for the uncoated lumen group), these results indicate that the inner lumens are heterogeneous surfaces. Most importantly, and corroborated by the SEM-X-ray analysis, the teflon-covered were not adequately coated. Recognizing the inherent difficulty in coating the narrow, 0.009" inner lumen, a teflon-lined polyimide lumen was extruded and tested. Nonetheless, loss of virus activity was still observed. It is known, however, that the processing of fluorinated polymers into catheter shafts requires the addition of additives. These materials, which include xylene, glycerine and octylphenoxypolyethoxyethanol, may have a significant effect on virus compatibility, highlighting the importance of testing the complete article components for biological activity.

CLAIMS:

19. The needle injection catheter of claim 18, wherein said polymeric material comprises a material selected from polyalkylene polymers and copolymers, fluorocarbon polymers and copolymers, polyester polymers and copolymers, polyether polymers and copolymers, silicone polymers and copolymers, and polyurethane polymers and copolymers.

26. The needle injection catheter of claim 25, wherein said polymeric material comprises a material selected from polyalkylene polymers and copolymers, fluorocarbon polymers and copolymers, polyester polymers and copolymers, polyether polymers and copolymers, silicone polymers and copolymers, and polyurethane polymers and copolymers.

[0049] Alternatively, by selecting biocompatible microparticles, the microparticles can be administered to a patient along with the therapeutic agent. Referring again to the Examples below, the latex polystyrene beads are tissue compatible and may be injected along with the viral particles to the patient. Injection of the beads is believed to enhance both cellular gene transfer and in vivo stability.

[0050] In many preferred embodiments of the present invention, the microparticle suspensions are administered to patients via drug-delivery medical devices and accessories. Contemplated medical devices are numerous. For example, the medical devices contemplated for use in connection with the present invention can be those used for systemic treatment or those used for local treatment of a tissue or organ. Non-limiting examples include tumors; organs including but not limited to the heart, lung, brain, liver, kidney, bladder, urethra and ureters, eye, intestines, stomach, pancreas, ovary, and prostate; skeletal muscle; smooth muscle; breast; cartilage; and bone.

[0051] Essentially any medical device for parenteral injection (i.e., administration by a route other than the alimentary canal, including subcutaneous, intramuscular, intravenous, intravascular, intraorbital, intracapsular, intraspinal and intrasternal administration) is contemplated for use in connection with the present invention.

[0052] Preferred medical devices include catheters, including endoluminal catheters such as needle injection catheters (e.g., for endocardial, epicardial, and pericardial agent administration), balloon catheters, diagnostic catheters and perfusion catheters, conventional needle syringes, hypodermic needles, intravenous injection devices, biopsy needles and devices, tissue ablation devices, aspirating needles, stents, and so forth. Specific examples of devices for drug delivery to the heart include, for example, those found in the following patents and patent applications: US 5,450,846, US 5,840,059, US 5,878,751, US 5,551,427, US 5,931,834, US 5,925,012, US 5,925,033, US 5,538,504, WO 99/39624, WO

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L3: Entry 1 of 1 File: PGPB May 9, 2002

DOCUMENT-IDENTIFIER: US 20020055721 A1
TITLE: Biocompatible pharmaceutical articles

Detail Description Paragraph:
[0048] Specific pharmaceutical articles that are appropriate for the practice of the present invention include the following: (1) manufacturing articles, including fermentors, glassware, plasticware, probes and tubing; (2) storage and transport articles, including storage vessels, transport vessels, stoppers, lids and septums; (3) analytical articles including needles, pipette tips, cell culture apparatus and analytical equipment; (4) medical devices, including conventional needle syringes, hypodermic needles, intravenous injection devices, biopsy needles and devices, tissue ablation devices, aspirating needles, catheters, including endoluminal catheters such as needle injection catheters (for endocardial, epicardial, and pericardial agent administration), balloon catheters and diagnostic catheters and perfusion catheters, filters, grafts, metallic and polymeric stents, including those having a polymer coated thereon for delivery of pharmaceutically active materials, aneurysm filling coils, transmyocardial revascularization devices, percutaneous myocardial revascularization devices, soft tissue clips, sutures, blood clot filters, implants or spikes (polymeric or metallic); and (5) medical device accessories, including adhesives, coatings, balloons, membranes, manifolds, hubs, fittings, stopcocks, valves, tubing kits, manifolds, wires, syringes, microspheres or nanoparticles, and so forth.

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L12: Entry 6 of 22 File: PGPB Mar 27, 2003

DOCUMENT-IDENTIFIER: US 20030059520 A1
TITLE: Apparatus for regulating temperature of a composition and a method of coating implantable devices

Detail Description Paragraph:
[0013] FIG. 1 additionally illustrates a stent 24 mounted on a mandrel 26. Mandrel 26 can be coupled to a motor assembly 28 for providing rotational motion and/or transitional motion along railing 30 to stent 24. Stent is broadly intended to include self-expandable stents, balloon-expandable stents, and stent-grafts. One of ordinary skill in the art, however, understands that the apparatus and method of the invention can be used to coat other medical devices, such as grafts (e.g., aortic grafts), artificial heart valves, cerebrospinal fluid shunts, axius coronary shunts, pacemaker electrodes, and endocardial leads (e.g., FINELINE and ENDOTAK, available from Guidant Corporation). The underlying structure of the device can be virtually any design. Stents are typically defined by tubular body having a network of bands or cylindrical elements interconnected by, for example, connecting elements. The particular structure of the stent is not of critical significance. The device can be made of a metallic material or an alloy such as, but not limited to, cobalt chromium alloy (ELGILOY), stainless steel (316L), "MP35N," "MP20N," ELASTINITE (Nitinol), tantalum, nickel-titanium alloy, platinum-iridium alloy, gold, magnesium, or combinations thereof. "MP35N" and "MP20N" are trade names for alloys of cobalt, nickel, chromium and molybdenum available from standard Press Steel Co., Jenkintown, Pa. "MP35N" consists of 35% cobalt, 35% nickel, 20% chromium, and 10% molybdenum. "MP20N" consists of 50% cobalt, 20% nickel, 20% chromium, and 10% molybdenum. Devices made from bioabsorbable or biostable polymers could also be used.